Statement By

Dr. Katherine Kelley

President-Elect, Association of Public Health Laboratories

Director of Public Health Laboratories

Connecticut Department of Public Health

On

Assessing Anthrax Detection Methods

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Association of Public Health Laboratories

2025 M Street, NW Suite 550
Washington, DC 20036-3320

Phone: 202.822.5227
Fax: 202.887.5098

Web: www.aphl.org

Mr. Chairman, Members of the Committee, thank you for the opportunity to testify on assessing anthrax detection methods.

My name is Dr. Katherine Kelley and I am here today representing the Association of Public Health Laboratories, APHL. I am currently the Director of the Connecticut Department of Public Health Laboratory. As its name implies, APHL is the association for state and local governmental laboratories that perform testing of public health significance. In the area of terrorism response, that includes both human and environmental testing. This work is done through key partnerships with the Centers for Disease Control and Prevention (CDC) and the Federal Bureau of Investigation (FBI) to provide rapid local response to a biological event using consistent scientific methods and reagents, and nationally-accepted evidentiary practices. The structure for these partnerships is the Laboratory Response Network (LRN).

The LRN was deployed in response to the mail contamination events post-9/11. In some states, the laboratory role was limited to testing of mail distribution centers in support of an early survey to assess the extent of contamination. In other states, such as Connecticut, the laboratory participated in the diagnosis of infected people, in clinical investigations to find the source of their infection, in environmental investigations of the postal distribution system as a possible source of anthrax, and in the environmental clean up and clearance of contaminated sites. All of this work was carried out under the direction of a Joint Command Center made up of experts from CDC, the Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), the United States Postal Service (USPS) and APHL, and drew on outside experts as needed.

APHL agrees with the recommendations of the GAO report under consideration today. There continues to be a need for agreed-upon, validated methods for clinical specimens and environmental samples in the various approaches to laboratory testing. However, four years after the events it is easy to overlook the highly-charged, complex situation of that moment in this nation's history. I would like to use our experience in Connecticut as an example. The Connecticut Department of Public Health (DPH) received CDC funding to build laboratory response capacity for Weapons of Mass Destruction (W – M – D) bio-agents. The working hypothesis at the time was that the LRN would be responding to human outbreaks caused by biothreat agents and that most, if not all, of the testing would be of human clinical specimens.

As a follow-up to the anthrax letters sent to Congress, our laboratory assisted USPS in an assessment of three postal distribution centers in Connecticut. On November 11, 2001, our laboratory tested 53 samples from the Wallingford USPS Distribution Center as part of an assessment of facilities that might have been contaminated by the Daschle or Leahy letters. All samples tested negative, but the machine that processed the mail to Oxford and Seymour was not sampled. On November 19, 2001, a local hospital contacted the Connecticut State Health Department to report a suspected anthrax case in an elderly woman from Oxford, CT. Blood culture specimens were transported to the

Connecticut Department of Public Health Laboratory (DPH Laboratory) from Oxford and they tested positive for anthrax using LRN methods. CDC and the FBI were notified immediately. On November 20, 2001, CDC retested the specimens and confirmed anthrax. Assuming that this was the index case of a potential anthrax outbreak, CDC was asked to provide assistance and a team of epidemiologists was dispatched to Connecticut. In the interim the FBI and Connecticut state police secured the patient's home. Over the course of the next few weeks, CDC and state epidemiologists collected samples from all locations that the patient had visited just before she had experienced symptoms and from every part of her home. The DPH laboratory tested them and all were negative for the anthrax bacillus (*Bacillus anthracis*.) One of the CDC epidemiologists was familiar with the USPS barcode system for tracking first class mail. These data were reviewed to see if any mail coming in close proximity to the Daschle or Leahy letters had gone to Oxford or Seymour, Connecticut. One such letter was identified and retrieved for testing. It was positive for anthrax spores even after repeated sampling.

This link to anthrax-positive mail directed the investigation to the Wallingford Postal Distribution Center and to more targeted sampling of the machines that processed mail to the Oxford/Seymour route. In all, the DPH Laboratory tested 465 clinical specimens and over 1,500 environmental samples related to this case. Regardless of the contractor, method of sampling or testing method there were no sites that gave inconsistent results prior to decontamination. This work was performed with continual input from federal experts and utilized lessons that were being learned from the Florida, Washington and New Jersey investigations. There was constant communication between the Joint Command Center and the DPH Laboratory regarding testing capacity, methodology and unusual samples. We were all under intense pressure from our leadership and the press for quick, accurate information. Our laboratory maintained double shifts daily for three months. I am extremely proud of the work done by staff and their dedication to quality science and public health.

To this day no direct link has been made between the Oxford patient and contaminated mail. The assumption is that she may have been exposed to cross-contaminated mail and that this mail had been disposed of prior to her admission to the hospital. It is further assumed that her advanced age and poor health made her more vulnerable to infection.

As I indicated at the start of my testimony, APHL agrees with the recommendations of the GAO report and we continue to press for the development of agreed-upon, validated methods for clinical specimens and environmental samples in the various approaches to laboratory testing.

I would be remiss if I did not also mention the challenges associated with a response to a chemical terrorism event.

- Federal funding has improved the ability of public health laboratories to measure chemical substances in people exposed to a toxin. There is still much work to be done to increase the capability and capacity of these laboratories. None of these

federal resources have developed any capability or capacity for public health laboratories to accurately measure for chemicals in samples that do not come from people such as swabs taken from the scene of an incident; clothing from those effected, or even the actual chemical substance.

- There is no comprehensive plan in place today for a response to a chemical terrorism event and there are only three Department of Defense laboratories that could safely and effectively analyze these materials. Currently public health laboratories are not privy to the analytical methods and check standards that have been developed by the Department of Defense, and thus have no ability to perform analyses in a validated and standardized method. In the absence of these materials, public health laboratories will be limited to clinical testing in the response to a chemical event, and will not be able to assist in determining the substance involved in the contamination or its source. This situation is unacceptable, and must be addressed prior to an actual event. Sharing the Department of Defense methods and protocols would be a very good start.

Once again, thank you for the opportunity to testify today and I would be happy to answer any questions.